K070427

MAY 14 2007

Empi®

510(k) Summary

510(k) Owner's Name:	Empi
Address:	599 Cardigan Rd. St. Paul, MN 55126
Phone number:	651-415-7344
Fax number:	651-415-7497
Email:	swalrod@empi.com
Contact person:	Sandra Walrod, Regulatory Affairs Associate
Date prepared:	February 9, 2007
Trade name:	Empi Dupel® Transport Iontophoresis System
Common name:	Iontophoresis Device
Classification name:	Iontophoresis Device (21 CFR 890.5525)
Product Code:	EGJ
Classification:	Class III
Predicate devices:	Empi Action Patch® Iontophoresis System (K030395), Empi Dupel® Iontophoresis System (K915444), Empi Dupel B.L.U.E.® Iontophoresis Electrode (K970491, K983484)

Device Description:
The Empi Dupel Transport Iontophoresis System is a disposable, single-use iontophoresis device with a self-contained battery and electrical circuitry. The system includes a power module, delivery electrode, return electrode and lead wires. The Dupel Transport is capable of delivering both negatively and positively charged ionic solutions. The device uses a microprocessor to precisely control the delivery time of 3 hours. An LED is utilized to confirm the device is turned on and provides an indication of how much time is remaining in the treatment period.

Intended Use:
The Empi Dupel Transport Smart Iontophoresis System can be used for the local administration of ionic solutions into the body for medical purposes and as an alternative to injections.

Comparison to predicate:

compared to the Action Patch Iontophoresis System. Like the Dupel Iontophoresis System the Dupel Transport is capable of delivering both negatively and positively charged ionic solutions. The Empi Dupel Transport Iontophoresis System uses the similar battery power source as the Empi Action Patch Iontophoresis System. The major differences between the Action Patch and the Dupel Transport are the ability to accommodate both positive and negative ionic drugs, the timing mechanism which is controlled by a microprocessor in the Dupel Transport and the case housing.

Non-clinical Testing:
Verification of the Empi Dupel Transport Iontophoresis System includes electrical and mechanical tests to show that the device meets its product specifications over a range of operating and storage conditions. Validation testing for the Dupel Transport Iontophoresis System includes testing to show the device meets user needs according to marketing requirements.

Clinical Testing:
No prospective clinical studies are required to demonstrate safety and efficacy of the in support of applications for regulatory approval/clearance in the target markets. The Dupel Transport Iontophoresis does not differ from the predicate devices in technological characteristics or intended use, where the device has a significant influence on clinical endpoints, and where prospective clinical studies would be necessary to determine safety and efficacy equivalence. The Product does not fit the profile of devices that might require clinical data per FDA guidance document 95-4158.

Conclusion:
The non-clinical testing demonstrates that the Empi Dupel Transport Iontophoresis System is substantially equivalent the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Empi
% Ms. Sandra Walrod
Regulatory Affairs Associate
599 Cardigan Road
St. Paul, Minnesota 55126

MAY 14 2007

Re: K070427
Trade/Device Name: Empi Dupel Transport Iontophoresis System
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: III
Product Code: EGJ
Dated: February 9, 2007
Received: February 13, 2007

Dear Ms. Walrod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to drugs for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-3 10)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class 11. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class 111 (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Brian Benson
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(240) 276-3805

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small

Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Empi Dupel Transport Iontophoresis System

Indications for Use:

The Empi Dupel Transport Smart Iontophoresis System can be used for the local administration of ionic solutions into the body for medical purposes and as an alternative to injections.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices